

### REMARKS

Claims 1-28, 30-36, 50, and 52-63 stand rejected. Claims 1, 13, 22, 27, 28, 50, and 53 have been amended, and new claims 64-69 have been added herein. The Examiner withdrew claims 37-49 from consideration. Thus, claims 1-28, 30-36, 50, and 52-69 are pending.

Claims 1, 22, 27, 28, and 50 have been amended to recite that the plants are male-sterile due to cytoplasmic male sterility or genetic male sterility. Support for these amendments can be found, for example, at page 26, lines 12-22, of the specification.

Claims 13 and 53 have been amended to replace nuclear male sterility with genetic male sterility. Support for these amendments and new claims 64-69 can be found, for example, in original claims 1, 22, 27, 28, and 50, and on page 26, lines 12-22, of the specification.

No new matter has been added.

Applicant requests reconsideration and allowance of claims 1-28, 30-36, 50, and 52-69 in view of the amendments and remarks herein.

### Double patenting

The Examiner provisionally rejected claims 1-28, 30-36, 50, and 52-63 on the ground of nonstatutory obviousness-type double patenting over claims 1-26 of copending Application No. 10/873,679.

Applicants request that the rejection be held in abeyance until there is an indication of otherwise allowable subject matter.

### Rejections under 35 U.S.C. § 112, first paragraph

#### *Written Description*

The Examiner rejected claims 1-28, 30-36, 50, and 52-63 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner stated that there is no guidance "presented for the isolation or characterization of any other transcription activator-encoding sequences or any other transcription activator recognition sequences, or plants transformed therewith." Office Action of June 1, 2006, at page 3. The Examiner further stated that the fact patterns involved in *Capon v. Dudas* are different from the instant application. Specifically, the Examiner stated that in *Capon v. Dudas*, the claims

encompassed the well-developed antibody art, while the present application involves the art of plant transformation with transcriptional activator-encoding sequences.

Applicant respectfully disagrees.

The specification provides a description of transcription activators and their cognate recognition sequences at page 21, lines 1-15. Such transcription activators would have been well-known to one of ordinary skill in the art as of the filing date of the present application. In fact, at the time of filing, a database of plant transcription factors and recognition sequences was available. See, Higo *et al.* (*Nucleic Acids Research*. 27(1):297-300 (1999)) and PLACE database release 11.0 ([http://ftp.dna.affrc.go.jp/pub/dna\\_place/r11.0/place.seq](http://ftp.dna.affrc.go.jp/pub/dna_place/r11.0/place.seq); September 10, 2002). Table 1 contains a non-exhaustive list taken from the above-identified database of plant transcription activators that were known at the time of filing and accession numbers for their cognate recognition sequences. There are 32 transcription activators in Table 1, indicating that at least 32 transcription activators were known to one having ordinary skill in the art as of the priority date of the present application. Thus, Applicant submits that the specification, as assessed from the viewpoint of one having ordinary skill in the art, provides adequate written description for claims 1-28, 30-36, 50, and 52-63.

Table 1. Plant transcriptional activators and recognition sequences.

Transcription activator	Species	PLACE Database accession number (Release 11.0; September 10, 2002)
ABF	Rice	S000190
ABI3	Brassica	S000145
Apetalla3/Pistillata heterodimer	Arabidopsis	S000347
ARF1	Arabidopsis	S000270
ARF1	Soybean	S000337
ASF-1	Pea	S000023
ASF-1	Tobacco	S000023, S000073, S000024, S000240
AtEBP/AtERF	Arabidopsis	S000036, S000232
Beta-1 factor	Maize	S000027

CBF1	Arabidopsis	S000152
CBF2	Maize	S000133
CPRF1	Parsley	S000333, S000313
CPRF2	Parsley	S000333, S000313
CPRF3	Parsley	S000313
CPRF4	Parsley	S000333
DREB1	Arabidopsis	S000152
DREB2	Arabidopsis	S000152
E2F	Arabidopsis	S000366
E2F	Tobacco	S000367
EIN3	Arabidopsis	S000332
EMBP-1	Wheat	S000015, S000119
OsE2F1	Rice	S000396
OsE2F2	Rice	S000396
PG13	Tobacco	S000335
RISBZ1	Rice	S000277
SGBF-1	Tobacco	S000016
STK	Potato	S000398
TAF-1	Rice	S000007
TAF-1	Tobacco	S000019
TRAB1	Rice	S000299, S000281, S000282
WRKY1	Parsley	S000142
WRKY2	Parsley	S000142

In light of the above, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, for lack of written description.

*Enablement*

The Examiner rejected claims 1-28, 30-36, 50, and 52-63 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Examiner

stated that gene modulation in transgenic plants via heterologous transcription activators is unpredictable as demonstrated in the Lloyd *et al.* (*Science*. 266:436-439 (1994)) and Schena *et al.* (*Proc. Natl. Acad. Sci. USA*. 88(23):10421-5 (1991)) publications, in part because codon optimization of transcription activator-encoding sequences was not taught in the specification.

Applicant respectfully disagrees.

The present claims are fully enabled. The present specification provides detailed guidance regarding the practice of the claimed methods. For example, guidance for practicing methods for making infertile seed is provided at page 16, line 12 to page 13, line 15. The specification also provides guidance for making and using the claimed plants at page 25, line 16 to page 28, line 8.

The state of the art is not static in time, and must be evaluated based on the filing date. MPEP § 2164.05(a). Here, the Lloyd *et al.* and Schena *et al.* publications are not indicative of the state of the art at the time of filing, as evidenced by Bruce *et al.* (*Plant Cell*. 12:65-79 (2000)), and the Streatfield publication (*Plant Biotechnology*. 5:2-15 (2007)), in the attached Information Disclosure Statement. The Streatfield publication reviews codon optimization as a method for increasing recombinant protein production in plants, and cites Rouwendal *et al.* (*Plant Mol. Biol.* 33:989-999 (1997)), Batard *et al.* (*Arch. Biochem. Biophys.* 379:161-169 (2000)), and Streatfield *et al.* (*Vaccine*. 19:2742-2748 (2001)), each attached in the accompanying Information Disclosure Statement, as examples of codon optimization. See, page 7, second column, and Table 2 of the Streatfield publication. In view of the knowledge in the art regarding transcription activator coding sequences, transcription activator recognition sequences, codon optimization, and the guidance provided in the specification, one of ordinary skill would have been able to make and use the claimed invention.

In light of the above, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement

#### Rejections under 35 U.S.C. § 102

The Examiner rejected claims 50, 53-54, and 56-60 under 35 U.S.C. § 102(e) as being anticipated by Crossland *et al.* (U.S. Patent No. 6,362,394). The Examiner also rejected claims 50, 53-54, and 57-60 under 35 U.S.C. § 102(b) as being anticipated by Goff *et al.* (U.S. Patent

No. 6,147,282). Specifically, the Examiner stated that the Crossland *et al.* and Goff *et al.* references teach nuclear transgenes that confer male sterility, and that a nuclear transgene may be considered nuclear or genetic male sterility.

Applicants respectfully disagree.

Present claim 50 is directed to a plant that is male-sterile due to cytoplasmic or genetic male sterility. Present claim 50 thus excludes molecular male sterility due to a transgene, which falls in a separate class in the specification. See page 26, lines 12-22, of the specification. Further, the present claims are directed toward plants that produce infertile seeds. Such seeds are infertile because they contain a sequence causing seed infertility. In contrast, the Crossland *et al.* and the Goff *et al.* publications are directed to plants comprising a transgene that can be used to control fertility. See, e.g., Crossland *et al.* at column 2, lines 1-51 and Goff *et al.* at column 2, lines 45-66. The Crossland *et al.* and the Goff *et al.* publications also do not teach plants that produce infertile seeds. Instead, the Crossland *et al.* and the Goff *et al.* publications teach seedlessness. Thus, the Crossland *et al.* and the Goff *et al.* publications do not teach each and every limitation in the claims and do not anticipate claims 50, 53-54, and 56-60.

In light of the above, Applicant requests that the rejection of claims 50, 53-54, and 56-60 under 35 U.S.C. § 102(e) be withdrawn.

#### Rejections under 35 U.S.C. § 103

The Examiner rejected claims 1-18, 21-28, 30-36, 50, and 52-63 under 35 U.S.C. § 103(a) as being unpatentable over each of Crossland *et al.* and Goff *et al.* in view of Harada (U.S. Patent No. 6,781,035). The Examiner also rejected claim 19 under 35 U.S.C. § 103(a) as being unpatentable over each of Crossland *et al.* and Goff *et al.* in view of Harada *et al.*, in further view of Fisher *et al.* (U.S. Patent No. 6,906,244) and Fisher *et al.* (U.S. Patent No. 6,229,064). The Examiner also rejected claim 20 under 35 U.S.C. § 103(a) as being unpatentable over each of Crossland *et al.* and Goff *et al.* in view of Harada *et al.*, in further view of Fisher *et al.* (U.S. Patent No. 6,559,357).

Applicant respectfully disagrees.

The cited references do not render the present claims unpatentable. Further to the above, the present claims are limited to methods and compositions involving plants that are male-sterile

due to cytoplasmic or genetic male sterility. The presently claimed methods also involve the formation of infertile seeds after carrying out a cross with a plant expressing a transcription activator. The Crossland *et al.* and the Goff *et al.* publications do not teach or suggest plants that are male-sterile due to cytoplasmic or genetic male sterility. The Crossland *et al.* and the Goff *et al.* publications also do not teach or suggest plants that produce infertile seeds. Thus, neither the Crossland *et al.* publication nor the Goff *et al.* publication suggest the use of a coding sequence that results in seed infertility in combination with cytoplasmic or genetic male sterility.

Harada does not remedy the deficiencies of the Crossland *et al.* and the Goff *et al.* publications because there is no motivation to combine Harada with either of the primary references and, even if combined, the references do not teach or suggest every element of the claimed invention. Similar to the Crossland *et al.* and the Goff *et al.* publications, the Harada *et al.* publication does not teach or suggest the use of plants that are male-sterile due to cytoplasmic or genetic male sterility. Harada instead suggests the use of a LEC1 transgene to create male-sterile plants. See, the Harada *et al.* publication at column 11, lines 34-37. Thus, the combination of the Crossland *et al.* or the Goff *et al.* publication with the Harada *et al.* publication does not render the present claims obvious.

With respect to claims 19 and 20, the three Fischer patents do not remedy the deficiencies of the Crossland *et al.*, the Goff *et al.* and the Harada *et al.* publications because the Fischer patents do not teach or suggest that one should use plants that are male-sterile due to cytoplasmic or genetic male sterility. On the contrary, the Fischer patents suggest that FIE, MEA or ANT expression be modulated by transgenes for the purpose of making male-sterile plants. See, Fischer '244 at column 17, line 58 to column 18, line 9; Fischer '064 at column 9, lines 44-65; and Fischer '357 at column 8, lines 43-59. Thus, the combination of cited references do not teach or suggest every element of the claimed invention.

In view of the above, Applicant requests that the rejection of claims 1-28, 30-36, 50 and 52-58 under 35 U.S.C. § 103(a) be withdrawn.

### CONCLUSION

Applicant submits that claims 1-28, 30-36, 50, and 52-69 are in condition for allowance, which action is respectfully requested.

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Serial No. : 10/667,295  
Filed : September 17, 2003  
Page : 18 of 18

Attorney's Docket No.: 11696-047001

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment. The Examiner is invited to telephone the undersigned agent if such would further prosecution.

Please any charges or credits to Deposit Account 06 1050.

Respectfully submitted,

Date: Feb 15, 2007

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